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UNCLAS SECTION 01 OF 03 WELLINGTON 000489

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SUBJECT: STATUS OF RECENT NEW ZEALAND INTELLECTUAL PROPERTY  
AND TELECOMMUNICATION DEVELOPMENTS

REF: WELLINGTON 158

1. (U) SUMMARY: New Zealand remains embroiled in a politically contentious battle over access to medicines and regulatory reform of its pharmaceutical industry. Recent legislation aimed at linking a proposed to create a joint Australia - New Zealand regulatory body (ANZTPA) along with stricter marketing regulations (e.g. labeling standards) for pharmaceuticals has failed in Parliament, for now. The national drug-funding agency, Pharmac, is currently facing a historic legal challenge in the High Court, which has the potential to loosen the agency's assessment criteria and review processes for determining which new drugs are made available to NZ consumers. Broader proposed reforms to bring copyrights, patents and trademarks legislation up to international standards continue to move slowly forward in Parliament. The telecommunications industry is feeling the pressure of the Ministry of Communication's attempts to advance its liberalization plan and increase market competition through unbundling telecommunication services. After years of delay, there is renewed hope that New Zealand's largest telecom provider, Telecom New Zealand, now under new management, will finally implement needed liberalization and modernization. End Summary

Reform of Pharmaceuticals still politically contentious  
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2. (U) New Zealand had been working with Australia for more than 10 years to develop a joint regulatory scheme for therapeutic products and to set up a new trans-Tasman agency, in line with a trans-Tasman treaty signed in 2003, called the Australia New Zealand Therapeutic Products Authority (ANZTPA), to oversee the scheme. This proposed agency would have replaced Australia's Therapeutic Goods Administration and New Zealand's Medsafe. Expected to have been based in Canberra and Wellington, it was designed to be run by a managing director and governed by a board overseen by a council comprising the two countries' health ministers. It would have regulatory authority over all medicines, medical and surgical devices, and complementary/alternative medicines. This includes prescription and over-the-counter medicines, contact lenses, pacemakers, endoscopes, blood products and, most controversially, most herbal and traditional medicines, sunscreens, homeopathic remedies, aromatherapy, vitamins, minerals and other dietary supplements. In a deliberate concession to NZ political sensitivities, it would not regulate- but not products

prepared by traditional Maori healers for individual clients.

13. (U) In mid June, the NZ's Parliamentary select committee charged with considering the Therapeutic Products and Medicines Bill had been unable to reach agreement, and therefore could not recommend the bill be passed. The select committee received 895 submissions, three quarters of which were from individuals, generally opposed to the regulation. Opponents have said regulation would impose unnecessarily prohibitive compliance costs that would squeeze out smaller producers, limiting consumer choice. Many felt the regulations were overly onerous for low-risk therapeutic products. The impasse left the bill in the hands of the Government to salvage. The bill squeaked through its first reading on a vote of 61 to 60, but the Government's ability to pass it has been in doubt since independent MPs Taito Phillip Field and Gordon Copeland said they would vote against it. As of the end of June, the bill effectively died after all attempts to find a compromise and reformulate the text failed.

14. (U) Currently there is minimal regulation of medical devices and "complementary" (i.e., non-prescription) medicines in New Zealand, which some see as out of step with international best practices. The proposed bill also set out the direction regulations for advertising of therapeutic products in New Zealand. Direct to consumer advertising (DTCA) of prescription medicines would have been permitted, however under the scheme there would also have been controls to ensure consumers are provided with balanced and truthful information about the therapeutic health benefits of medicines so that they can make more informed choices.

WELLINGTON 00000489 002 OF 003

Court case could shape future access to medicines  
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15. (U) For the first time in NZ, a citizen's group is challenging the GNZ's drug-funding agency, Pharmac, in the High Court. Seven breast cancer patients and a member of the Breast Cancer Aotearoa Coalition, filed documents in the High Court of New Zealand on June 29th against Pharmac's decision to restrict treatment to a 9-week course of therapy rather than funding a full 12 month course of Herceptin for women with early stage breast cancer. Cost of a year's treatment range between US\$75,000 and US\$90,000.

16. (U) This case challenges Pharmac's approval processes and assessment criteria for drugs that are funded under the national health care system. It is indicative of increasing public dissatisfaction with the GNZ limiting access to pharmaceuticals through the single drug-funding agency. If successful the case would force a revision of Pharmac's approval processes and assessment criteria, potentially increasing market access for US companies.

Copyright legislation still under scrutiny  
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17. (U) The Copyright Amendment Bill currently remains under the consideration of the Parliamentary Commerce Select Committee. The bill amends the Copyright Act 1994 (the Act) intended to clarify the application of existing rights and update the Act to take account of changes in recent technology and international treaty obligations. The Committee has received an extension for ongoing deliberations, and it is not expected to return the bill to the parliament for a third and final reading before the end of July.

Patent legislation expected to meet little resistance  
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18. (U) The new draft patent bill has been remained on the parliamentary docket for some time now, but according to a

source at the Ministry of Economic Development (MED), it will most likely be introduced over the next three months and no later than the end of this year. Modeled largely after current British patent law, the GNZ drafters had hoped to capture the UK's experience in conforming to its patent regime to EU standards. An unofficial preliminary draft version of the bill, called an "exposure draft," was initially released in 2005 and received only technical comments as to the form of the bill. These have been reviewed and applied as appropriate. Despite the bill's long gestation period, MED attorneys responsible for drafting feel that the bill is likely to pass with little additional modification.

#### Trademarks - GNZ moving towards WIPO compliance

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¶9. (U) MED is also currently amending existing trademark legislation to incorporate recent World Intellectual Property Organization (WIPO) treaties. These amendments are expected to bring GNZ in compliance with the recent WIPO trademark treaties otherwise referred to as the Madrid, Singapore and Nice treaties. Under the new legislation, investigation and enforcement provisions will be enhanced, and compliance responsibilities will be given to directly to MED, which will have the enhanced capacity to properly investigate claims and enforce regulations. MED expects to have the bill fully drafted by the end of 2007 and introduced to parliament by beginning of 2008.

#### Telecommunications reform in flux

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¶10. (U) In December 2006 the parliament passed a program of market reforms - The Telecommunications Amendment Act - and introduced a timetable for restructuring the state-owned telecommunications enterprise, Telecom NZ, which includes enhanced competition through unbundling local loop (LLU), local loop co-location and bitstream access. An industry-wide process to determine the terms for unbundling started in February 2007. Though Telecom NZ remains on track to meet

WELLINGTON 00000489 003 OF 003

the government's timetable for unbundling, Telecom NZ executives did submit a request for an extension of their time frame for LLU. The Commerce Commission (ComCom - functions similar to FCC) rejected Telecom NZ's request. This action on the part of GNZ is seen by industry analysts as a sign that the GNZ wants no further delays and its relationship with Telecom NZ is no longer business as usual.

¶11. (U) On 1 May 2007, the Ministry of Communications (a part of the Ministry of Economic Development - MED) invited comment on Telecom's proposal to separate wholesale and retail operations as it implements local loop unbundling (LLU terms open to public comment as of June 13). ComCom is expected to finish a first round draft of terms by end of July based on the industry submissions although some market analysts remain pessimistic about pace of liberalization. Some have commented that, despite MED's efforts at modernization, the lack of technological investment over the past 25 years remains a hurdle in upgrading current infrastructure.

¶12. (U) Finally, Telecom NZ has just appointed United Kingdom's Telco executive Dr Paul Reynolds as its new chief executive to succeed Theresa Gattung. Reynolds is currently chief executive of BT (British Telecom) Wholesale, an arm of UK-based Telco and information technology firm - BT Group. Although Post is unsure of Reynolds' ultimate plans regarding Telecom NZ modernization, he does have a reputation as an agent of change while at BT. This has led to renewed hope in local government and industry that Telecom NZ will finally implement needed liberalization and modernization.

¶13. (U) COMMENT: Although recent media reports reveal that

the left-leaning Government and the small right-wing ACT Party have tacitly agreed to have an open dialogue regarding the Therapeutic Products and Medicines bill, Post believes it is unlikely to result in a political union to support the bill. (Note. If Labour secured ACT's two votes in Parliament it would have enough votes to pass the bill through Parliament. End Note.) It is likely that the ideological gulf between Labour and ACT on the issue of regulation - Labour is pro-regulation and ACT is fervently anti-regulation - would be a step too far for the two parties to team up and support this particular bill. Post believes that ACT's motivation was less to do with working with Labour to progress this particular bill and more to do with heightening the party's profile. END COMMENT.  
MCCORMICK